White Paper:
Policy Issues in Planning and Regulating Open Heart Surgery Services in Maryland

Analysis of Public Comments and Staff Recommendations

MARYLAND HEALTH CARE COMMISSION

September 15, 2000

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I. INTRODUCTION

On June 18, 2000, the Commission released for public comment a ***White Paper: Policy Issues in Planning and Regulating Open Heart Surgery Services in Maryland***. This White Paper was prepared to assist the Commission in the process of updating the State Health Plan for Cardiac Surgery and Therapeutic Catheterization Services by: (1) providing background information on cardiac care services in Maryland; (2) identifying key policy issues in planning and regulating open heart surgery services; (3) examining the impact of alternative policy assumptions; and (4) providing a framework for the Commission to obtain public comment on key policy issues prior to updating the State Health Plan.

In response to the invitation for public comment, written comments were received from a total of 21 organizations and individuals. A summary of those written comments is provided in the ***White Paper: Policy Issues in Planning and Regulating Open Heart Surgery Services in Maryland--Summary of Public Comments*** (September 15, 2000). In addition, a complete set of the written comments received on the White Paper may be obtained by contacting the Division of Health Resources.

The purpose of this document is to analyze the public comments received on the White Paper and provide a staff recommendation on the key issues for consideration by the Commission. This document is organized to correspond to the policy options identified in the White Paper: (A) Need Projection Policies; (B) Quality of Care Policies; (C) Cost of Care Policies; (D) Access to Care Policies; and (E) Other Policies.

II.
EXECUTIVE SUMMARY

A. Need Projection Policies

1. Definition of Planning Regions

Staff believes that the four regions used for planning cardiac surgery in the current State Health Plan continue to appropriately recognize physician referral and patient migration patterns for specialized cardiovascular care services.

2. Length of Planning Horizon

One of the key issues in planning for the system of specialized cardiac care services is to assess the likely impact of trends that will shape the future environment. Given the potential for changes in the treatment of heart disease that could influence the organization of care, staff believes that the preferable policy direction is to use a three-year planning horizon in the update of the State Health Plan.

3. Use Rate Assumptions in Projecting Future Cases

The differences in use rates for adult open heart surgery services across planning regions suggest strongly that it is preferable to use regional rather than statewide experience in projecting future utilization. Staff recommends that the Commission use trended, regional use rates over the three year period 1997-1999 to project need in 2002. (Appendix 1 provides this calculation for the target year 2002 using the adjusted data for George Washington University Hospital)

4. Measurement of Program Capacity

Staff believes that the comments received on the measurement of program capacity suggest that the use of either physical operating room resources or historical utilization to quantify system capacity has significant limitations. Both approaches result in at best proxy indicators for system capacity. In the absence of a more comprehensive measure, staff recommends that the measurement of system capacity be changed as follows:

a. For new programs, capacity is defined as the greater of 350 cases or the actual number of cases during the first three years of a program's existence.
b. For programs older than three years, capacity is defined as the highest actual annual volume attained and reported by that program over the last three years subject to a market based constraint.
c. The capacity of any program cannot be greater than the higher of 800 cases or 50 percent of the projected gross need for the planning region.

(Refer to Table A-6 in Appendix 1 for the calculation of capacity using this recommended definition)

5. Patient Migration Patterns

Because a large number of factors influence where patients go for cardiac care services, actual utilization experience may be the best guide to future utilization patterns in the absence of being able to anticipate the impact of specific changes. Staff recommends that the Commission continue the policy of holding patient migration patterns constant between the base and target years of the need projection. It should be noted, however, that other aspects of the need methodology, notably measurement of capacity, may result in identification of need for new programs which will alter migration patterns in the future.

B. Quality of Care Policies

1. Minimum and Threshold Volume Standards - Open Heart Surgery and Coronary Angioplasty

For cardiac surgery services, a large volume of research studies have suggested lower mortality rates for programs performing higher volumes of procedures. Staff recommends cardiac surgical programs be required to perform a minimum of 200 cases annually to ensure quality of care; that programs be required to perform at least 350 procedures annually within three years of beginning operation; and that approval of a new cardiac surgery program not result in any program falling below 350 cases per year.

For angioplasty services, research studies have suggested improved outcomes for programs performing higher volumes of procedures. Staff recommends that angioplasty programs be required to perform a minimum of 200 cases annually to ensure quality of care.

2. Enforcement of Minimum Volume Standards

The relationship between the volume cardiac surgery cases and outcome suggests strongly that as a matter of public policy programs should meet minimum utilization levels. Given the importance of this issue, staff recommends that the Commission continue to require as a condition of Certificate of Need approval that a cardiac surgery program achieve minimum volume standards established in the State Health Plan within 24-months of beginning operation and maintain the minimum utilization level in each subsequent year of operation. On the question of whether existing programs should be required to meet a similar standard, the staff will make a recommendation on whether to change the current statute as part of its recommendations on the Certificate of Need working paper.

3. Outcome Data Reporting

Staff recommends that the Commission establish an Advisory Committee on Outcome Assessment in Cardiovascular Care to: (1) review available models and develop recommended approaches to outcome measurement in cardiovascular care, including cardiac surgery and angioplasty services; (2) develop a research agenda to advance the understanding of how cardiac care services should be organized to improve outcomes; and (3) develop recommendations on the appropriate governance, organizational structure, staffing, and funding for an on-going outcome assessment process for cardiovascular care. In establishing this Advisory Committee, the Commission should seek nominations from the Maryland Chapter of the American College of Cardiology, the Maryland Chapter of the American Heart Association, the Society of Thoracic Surgeons, the Medical-Chirurgical Faculty of Maryland, Maryland Hospital Association, and other appropriate organizations. Funding to support the work of the Advisory Committee on Outcome Assessment in Cardiovascular Care should be provided jointly by the Commission and hospitals.

4. Co-Location of Angioplasty and Open Heart Surgery Services

Staff recommends that: (1) the current policy requiring angioplasty procedures to be performed in hospitals with on-site cardiac surgery be maintained in the updated State Health Plan; and (2) the existing limited exemption for primary angioplasty performed in hospitals participating in the C-PORT project be continued. Staff believes that the C-PORT project has provided the opportunity for clinical research to guide State policy of oversight and that similar well-designed clinical research would contribute to improved patient care and more informed decision-making. Staff also believes that the Commission should consider a research project to assess whether it would be appropriate to modify current policy regarding the availability of cardiac surgical support for certain groups of elective angioplasty patients. This research project should be designed and implemented as a component of the Advisory Committee on Outcome Assessment in Cardiovascular Care.

C. Cost of Care Policies

1. Cost Effectiveness Standard

If need for additional cardiac surgery capacity is identified, staff believes that there is benefit to the public in encouraging applicants to make competitive rate offers as part of the Certificate of Need process. While the specific wording of this standard must be updated to be consistent with the recent changes to the HSCRC rate setting system, the policy approach has proven viable in the past and resulted in savings to the healthcare system that might not have otherwise been realized. At the same time, staff does not believe that cost considerations should receive greater weight than quality or access considerations. The cost effectiveness standard provides the

Commission with the ability to give preference to the most cost effective applicant where other considerations in the review process are equal. Staff recommends that the cost effectiveness standard preference policy be continued in the updated State Health Plan.

D. Access to Care Policies

1. Travel Time Standard

Staff believes that it is appropriate to continue using a travel time standard in the updated State Health Plan for Cardiac Surgery and Therapeutic Catheterization Services. This standard should refer to elective cardiac surgery and angioplasty services. Staff believes that the current 2-hour, one-way driving time for 90 percent of the population is a reasonable standard. At the same time, staff recognizes the need to consider developing other access measures, including time to treatment goals for certain sub-sets of patients, as pointed out in several of the comments received on travel time. One of the issues that should be addressed by the Advisory Committee on Outcome Assessment in Cardiovascular Care is the optimum timeframe for initiating primary angioplasty given current research and clinical practice.

E. Other Policies

1. Eligibility to Meet New Need

Staff recommends that the current policy of limiting the eligibility to meet identified new need for cardiac surgery services to hospitals without existing programs be continued in the updated State Health Plan.

2. Hospital Size

Staff recommends that the Commission: (1) continue to require applicants for new cardiac surgery programs to have an average daily census of at least 100 patients; (2) delete the policy pertaining to the size of the intensive care unit; and (3) develop indicators pertaining to the volume of cardiac patients for inclusion in the State Health Plan. With respect to the Size of Hospital policy, staff believes that the Commission should retain the ability to consider evidence as to why this policy should be waived.

3. Number of New Programs Allowed

Staff recommends that the Commission continue the policy of permitting the approval of one new cardiac surgery program at a time in each regional service area.

4. Preference Standards in Comparative Reviews

From a planning perspective, the use of preference standards in a highly competitive, comparative Certificate of Need review can provide an incentive for hospitals to

address important public policy issues. For this reason, staff recommends that the preference standards designed to promote cardiovascular disease prevention and outreach to minority populations be maintained in the updated State Health Plan. In addition, the updated State Health Plan should include a preference standard designed to encourage research in the area of cardiovascular diseases.

5. Exemptions from State Health Plan Policies

The current exemption policy maintains flexibility for the Commission to consider innovative research projects involving emerging technology without compromising important planning policies. Staff recommends that this policy be incorporated in the updated State Health Plan with a modification to permit hospitals to contribute funding for research projects under appropriate circumstances. This exemption policy would provide the Commission with the ability to conduct a study on whether it would be appropriate to modify current policy regarding the availability of cardiac surgical support for certain groups of elective angioplasty patients.

6. Relocation of Existing Cardiac Surgery Capacity Within Merged Asset Hospital Systems

Staff recommends that the Commission maintain the policy that a merged asset hospital system may not relocate any part of an existing cardiac surgery program to another hospital within its system without obtaining a Certificate of Need.

III.
POLICY AND REGULATORY ISSUES IN PLANNING OPEN HEART SURGERY SERVICES: ANALYSIS OF PUBLIC COMMENTS AND STAFF RECOMMENDATIONS

A. Need Projection Policies

1. Definition of Planning Regions

Analysis of Public Comments. Fifteen organizations submitted comments to the Commission addressing the issue of how to define planning regions for cardiac surgery services. The current State Health Plan for Cardiac Surgery and Therapeutic Catheterization Services establishes four planning regions as follows:

Table 1
Jurisdictions Included in the Planning Regions for Cardiac Surgery Services: COMAR 10.24.17

Planning Region	Jurisdictions Included
Western Maryland	Allegany County Frederick County Garrett County Washington County
Metropolitan Washington	Montgomery County Calvert County Charles County Prince George's County St. Mary's County Washington, D.C.
Metropolitan Baltimore	Anne Arundel County Baltimore City Baltimore County Carrol County Harford County Howard County
Eastern Shore	Caroline County Cecil County Dorchester County Kent County Queen Anne's County Somerset County Talbot County Wicomico County Worcester County

Seven of the organizations commenting on this planning policy recommended that the current four planning regions be maintained in the updated plan. Modifications to the current planning regions were recommended by seven organizations. One organization provided comments on the planning regions but did not provide a recommendation. Several commenters suggested that specialized cardiac care services, particularly primary angioplasty services, have evolved to the point where regionalization policies are no longer appropriate.

As noted in Table 1, the current State Health Plan chapter establishes four regional service areas for planning adult cardiac surgery services: Western Maryland; Metropolitan Washington; Metropolitan Baltimore; and Eastern Shore. In Western Maryland, one open heart surgery program has received Certificate of Need approval and is expected to begin operating later this year. In the Metropolitan Washington region (excluding Northern Virginia), six hospitals offer cardiac surgery services, including two hospitals in Maryland and four hospitals in Washington, D.C. Five hospitals in the Metropolitan Baltimore region provide cardiac surgery services, including four hospitals in Baltimore City and one hospital in Baltimore County. On the Eastern Shore, one hospital offers cardiac surgery services. Analysis of travel time data to existing cardiac surgery programs indicates that virtually all Maryland residents are within two hours, one-way driving time of at least one hospital that provides cardiac surgery services.

Comments on regionalization policies suggested that open heart surgery and coronary angioplasty services may have evolved to the point where it is no longer necessary to concentrate volumes in a smaller number of higher volume programs. If this were the case, it may be appropriate to consider planning on a county-level rather than regional basis. While increasing access to angioplasty services for acute myocardial infarction patients has the potential to improve patient care, staff believes that there are issues the remain to be studied regarding the use of this therapy. The steps taken by the Commission to increase access to angioplasty services via the C-PORT study while these issues are studied is a reasonable approach. At the same time, several comments noted the growing body of medical research suggesting that volumes are an important consideration in ensuring quality primary angioplasty programs. The current need for cardiac surgical backup to support elective angioplasty combined with the need to maintain adequate caseloads for angioplasty programs suggests a continuing need to regionalize open heart surgery and angioplasty services.

Regional planning helps to promote access to all levels of care in the most cost effective manner and ensures quality of care. The benefits of regionalization for specialized open heart surgery services include improved quality of care, training of highly skilled personnel, and advances in the treatment of heart disease. Accessibility to specialized open heart surgery services, particularly on an emergent basis, as well as cost effectiveness, and quality of care are enhanced by ensuring a sufficient caseload to develop and maintain the skills of specially trained personnel required to provide the service. Given these factors, the migration of patients across jurisdictional boundaries is particularly appropriate where open heart surgery services are concerned.

Staff Recommendation. Staff believes that the four regions used for planning cardiac surgery in the current State Health Plan continue to appropriately recognize physician referral and patient migration patterns for specialized cardiovascular care services.

2. Length of Planning Horizon

Analysis of Public Comments. A second component of the need projection policy involves the length of the planning horizon used to forecast the volume of expected open-heart surgery cases. Written comments were received from thirteen organizations on the length of the planning horizon. Eleven of those organizations expressed support for maintaining the current three-year planning horizon.

Traditionally, the State Health Plan has used a five-year horizon for planning the future development of health services and facilities. In the State Health Plan chapter on Cardiac Surgery and Therapeutic Catheterization Services, a shorter three-year planning horizon was first used with the update of the chapter that became effective December 1, 1997. A five-year planning horizon was used in the prior cardiac surgery plan chapter. The use of a shorter planning horizon in the current plan chapter is consistent with advice provided by the Technical Advisory Committee on Cardiovascular Services. In their December 1999 report to the Commission, Recommendation 1.0 states:

> *The Technical Advisory Committee recommends that the impact of emerging techniques in the medical and surgical treatment of heart disease be monitored and assessed every two years by the Commission to ensure that the State Health Plan reflects the implications of changes in cardiovascular care.*

Although advances in medical and surgical techniques for treating heart disease can be expected to modify future cardiac care use rates, data is not available to quantify the nature and magnitude of these potential changes. Commenters supporting the use of a shorter, three-year planning horizon cited the need for the Commission to monitor the trends in utilization of cardiac surgery, react quickly to changes that may occur in the delivery of care, and prepare more frequent updates of the plan to integrate the latest clinical standards.

Staff Recommendation. One of the key issues in planning for the system of specialized cardiac care services is to assess the likely impact of trends that will shape the future environment. Given the potential for changes in the treatment of heart disease that could influence the organization of care, staff believes that the preferable policy direction is to use a three-year planning horizon in the update of the State Health Plan.

3. Use Rate Assumptions in Projecting Future Cases

Staff Analysis of Public Comments. Another component of the need projection methodology for open heart surgery services that the Commission sought public comments on

are the assumptions concerning future use rates, or the volume of cases per 100,000 population. Policy 4.0 of the current State Health Plan provides that the Commission will use regional age-specific use rates in projecting future open heart surgery cases to accurately reflect regional differences in population characteristics, physician practice patterns, and other factors influencing utilization. This policy recognizes that substantial differences in use rates for open-heart surgery among the four regional service areas would be obscured with the use of statewide rates.

The current methodology calculates the average annual change in regional, age-specific use rates per 100,000 population over the most recent three year period and then compounds that rate of change between the base and target year to estimate a projected use rate. This projected use rate is then applied to the projected target year population by age group in three of the four regional service areas: Metropolitan Washington; Metropolitan Baltimore; and Eastern Shore. For the Western Maryland region, which does not currently have an open-heart surgery program, the State Health Plan currently uses base year (1999) age-specific use rates in projecting future cases.

Twelve organizations submitted comments concerning this component of the methodology. There was no consensus among those commenting on the preferable option. Four of the commenters recommended using 1997-1999 average regional use rates to guide the forecast of future cases. Three commenters supported the use of constant base year (1999) regional use rates. Other options suggested in the comments included: statewide use rate without trending; and an average of the regional use rate and the statewide use rate for each region. One of the comments suggested that missing data for George Washington University Hospital for 1999 be estimated for the purposes of the need projection analysis.

In 1999, hospitals in Maryland and Washington, D.C. performed 9,161 adult open heart surgery cases. (Table 2 displays trends in the number of adult open heart surgery cases over the six-year period, 1994-1999 with the adjustment for George Washington University Hospital.) Although there were substantial annual increases in the total volume of open heart surgery cases performed between 1994-1995, more recent data indicate a pattern of stable utilization. In each of the past two years, the volume of open heart surgery cases performed in Maryland and Washington, D.C. has increased by 1.5 percent or less. By comparison, between 1994-1995 and 1995-1996, open heart surgery volumes increased by 6.7 and 12.0 percent, respectively. Analysis of utilization trends by region shows that the number of adult open heart surgery cases performed in the Metropolitan Baltimore region peaked in 1997 and has declined in both 1998 and 1999. In the Metropolitan Washington region, the growth in annual cardiac surgical volumes continued through 1998 before moderating in 1999. Moderate annual increases in utilization have occurred throughout the six-year period, 1994-1999, for the Eastern Shore region.

Analysis of data on trends in the utilization of percutaneous transluminal coronary angioplasty shows that 13,624 procedures were performed during calendar year 1999 in Maryland and Washington, D.C. hospitals (Refer to Table 3). Similar to the experience with open-heart surgery services, more recent data show a pattern of moderate annual increases in overall volumes. While angioplasty volumes increased by almost 11 percent between 1996-1997 (from 10,920 to 12,094), data for the most recent time period indicate that volumes increased by only 4 percent between 1998-1999.

Table 2
Adult Open Heart Surgery Cases by Hospital:
Maryland and Washington, D.C., 1994-1999

Region/Hospital	Year					
	1994	1995	1996	1997	1998	1999
Metropolitan Washington Region						
Prince George's Hospital Center	59	81	90	61	91	120
Washington Adventist Hospital	925	723	839	899	817	817
Total Maryland	*984*	*804*	*929*	*960*	*908*	*937*
Georgetown University Hospital	542	444	451	328	301	140
George Washington University Hospital	148	150	118	65	85	85
Howard University Hospital	----	----	----	43	46	50
Washington Hospital Center	1,669	1,808	2,041	2,405	2,709	2,950
Total Washington, D.C.	*2,359*	*2,402*	*2,610*	*2,841*	*3,141*	*3,225*
Metropolitan Washington Total	**3,343**	**3,206**	**3,539**	**3,801**	**4,049**	**4,162**
Metropolitan Baltimore Region						
St. Josephs Hospital	842	1,008	1,269	1,388	1,411	1,308
Johns Hopkins Hospital	1,116	1,050	1,047	1,134	1,146	1,100
Sinai Hospital of Baltimore	473	444	577	416	477	541
Union Memorial Hospital	198	723	777	838	778	893
University of Maryland Hospital	785	713	818	775	553	596
Metropolitan Baltimore Total	**3,414**	**3,938**	**4,488**	**4,551**	**4,365**	**4,438**
Eastern Shore Region						
Peninsula Regional Medical Center	**360**	**448**	**475**	**482**	**536**	**561**
TOTAL	**7,117**	**7,592**	**8,502**	**8,834**	**8,950**	**9,161**

Source: Maryland Health Care Commission (Data reported for Maryland hospitals is from the Hospital Discharge Abstract Data Base for calendar years 1994-1999; data reported for Washington, D.C. hospitals for 1994-1996 is from a Survey of Cardiac Surgery and PTCA Services conducted by the Health Resources Planning Commission; data reported for Washington, D.C. hospitals for 1997-1998 is from a discharge data base provided by the D.C. State Health Planning and Development Agency; and data reported for Washington, D.C. hospitals for 1999 is estimated based on the discharge data base for January-June 1999. Howard University Hospital did not report data for 1994-1996 and George Washington University Hospital did not report data for 1999. For George Washington University Hospital, the volume of cases reflected for 1999 assumes the same level of utilization as experienced in the previous year.)

Table 3
Percutaneous Transluminal Coronary Angioplasty Cases by Hospital:
Maryland and Washington, D.C., 1994-1999

Region/Hospital	Year					
	1994	1995	1996	1997	1998	1999
Metropolitan Washington Region						
Prince George's Hospital Center	155	222	232	252	302	318
Washington Adventist Hospital	1,833	1,952	1,806	1,933	1,996	1,836
Total Maryland	*1,988*	*2,174*	*2,038*	*2,185*	*2,298*	*2,154*
Georgetown University Hospital	346	401	354	173	141	80
George Washington University Hospital	----	----	----	295	259	259
Howard University Hospital	----	----	----	32	52	56
Washington Hospital Center	3,041	3,066	3,048	3,332	3,683	3,986
Total Washington, D.C.	*3,387*	*3,467*	*3,402*	*3,832*	*4,135*	*4,381*
Metropolitan Washington Total	**5,375**	**5,641**	**5,440**	**6,017**	**6,433**	**6,535**
Metropolitan Baltimore Region						
St. Joseph's Hospital	1,269	1,528	1,664	1,592	1,820	1,775
Johns Hopkins Hospital	1,160	811	822	1,052	1,039	1,151
Sinai Hospital of Baltimore	652	740	757	778	764	848
Union Memorial Hospital	142	450	560	818	1,060	1,391
University of Maryland Hospital	571	541	579	591	588	538
Metropolitan Baltimore Total	**3,794**	**4,070**	**4,382**	**4,831**	**5,271**	**5,703**
Eastern Shore Region						
Peninsula Regional Medical Center	**776**	**909**	**1,098**	**1,246**	**1,153**	**1,386**
TOTAL	**9,945**	**10,620**	**10,920**	**12,094**	**12,857**	**13,624**

Source: Maryland Health Care Commission (Data reported for Maryland hospitals is from the Hospital Discharge Abstract Data Base for calendar years 1994-1999; data reported for Washington, D.C. hospitals for 1994-1996 is from a Survey of Cardiac Surgery and PTCA Services conducted by the Health Resources Planning Commission; data reported for Washington, D.C. hospitals for 1997-1998 is from a discharge data base provided by the D.C. State Health Planning and Development Agency; and data reported for Washington, D.C. hospitals for 1999 is estimated based on the discharge data base for January-June 1999. Howard University Hospital did not report data for 1994-1996 and George Washington University Hospital did not report data for 1994-1996 and 1999. For George Washington University Hospital, the volume of cases reflected for 1999 assumes the same level of utilization as experienced in the previous year.)

Staff Recommendation. The differences in use rates for adult open heart surgery services across planning regions suggest strongly that it is preferable to use regional rather than statewide experience in projecting future utilization. Staff recommends that the Commission use trended, regional use rates over the three year period 1997-1999 to project need in 2002. (Appendix 1 provides this calculation for the target year 2002 using the adjusted data for George Washington University Hospital)

4. Measurement of Program Capacity

Staff Analysis of Public Comments. To determine the need for new open-heart surgery capacity, the State Health Plan need projection methodology includes a component that estimates available system capacity. Comments regarding the measurement of program capacity were received from fifteen organizations. Four of those organizations supported the use of a capacity measure based on physical operating room space. Five organizations suggested that operating room resources be combined with other factors in measuring capacity. The measurement of program capacity based on historical utilization was supported by six organizations.

In the State Health Plan adopted in 1990, the capacity of existing cardiac surgery programs was defined as follows: the greater of 350 cases per hospital or the highest actual annual volume ever attained by the hospital in the most recent years of accurate available data; or if the hospital had not performed, for the past three consecutive years, at least 200 cases per year, the capacity of that program was measured by the actual volume of cases performed in that hospital during the base year.

The benchmark used to quantify available system capacity in the current State Health Plan reflects the number of operating rooms dedicated to the open heart surgery program. The measurement of the number of open heart surgery cases that can be performed in a single dedicated operating room used in the current plan reflects the assumption that 2.0 cases per day per operating room or 500 cases annually (assuming 5 days per week/50 weeks per year = 250 days) is a reasonable benchmark. This level of utilization is 80 percent of the defined capacity of 2.5 open heart surgery cases per day in a dedicated operating room recommended by the Technical Advisory Committee in 1997.

More recently, the Technical Advisory Committee reconsidered the previous recommendation regarding the capacity benchmark of 2.0 cases per operating room per day. In their December 1999 report to the Commission, the Technical Advisory Committee recommended that the capacity benchmark used in the current plan be eliminated and that the measurement of available system capacity be redefined to incorporate other factors such as monitoring of patient outcomes, assessment of future need, staff availability, access, and cost in determining the need for additional open heart surgery programs in Maryland.

The public comments received on the issue of measuring program capacity underscore the significant limitations of the two approaches used to date in the State Health Plan. For the approach based on physical operating room resources, those limitations include the fact that existing programs may add operating rooms without regulatory approval, that operating rooms are only a

small part of the clinical resources and cost associated with an open heart surgery service, and that use of operating rooms alone does not explicitly consider the availability of necessary staff. For the approach based on historical utilization those limitations include the fact that past caseloads do not necessarily reflect actual ability, and that past performance measures that has been done rather than what could be done.

Several of the comments received on the issue of program capacity noted that the Technical Advisory Committee had made recommendations on the measurement of program capacity. Although there were dissenting opinions filed, the Technical Advisory Committee made two recommendations on this issue in their 1999 report:

Recommendation 6.1

The Technical Advisory Committee recommends that the capacity benchmark used in the 1997 State Health Plan chapter on Open Heart Surgery (2.0 cases per operating room per day) be eliminated.

Recommendation 6.2

The Technical Advisory Committee recommends that the measurement of available system capacity be re-defined to incorporate other factors such as monitoring of patient outcomes, assessment of future need, staff availability, access, and cost in determining the need for additional open heart surgery program in Maryland.

The Technical Advisory Committee's report provides the context for these recommendations in the following discussion of the use of operating rooms to measure capacity:

Because operating rooms are only one component of an open heart surgery service, another factor that must be considered concerns whether the number of operating rooms is the most appropriate measure of program capacity. While the number of operating rooms may be a useful proxy for capacity at a specific point in time, this measure does not explicitly consider other important components of an open heart surgery program, including the number of open heart surgery teams and the availability of post-operative care facilities and staff. The use of dedicated operating rooms as the measure of capacity also does not consider how well the overall system functions to care for patients. Given these considerations, the Technical Advisory Committee believes that the current approach to measuring system capacity should be refined to consider additional factors, including waiting times, transportation issues, staffing, and program outcomes.

Another issue discussed in the comments concerns the differences between the cardiac surgery markets when Metropolitan Baltimore is compared with the Metropolitan Washington region. In those comments, it is suggested that the Metropolitan Washington region has fewer choices for patients as compared with the Metropolitan Baltimore region. The current State Health Plan includes only the six Maryland and Washington, D.C. open heart surgery providers in the Metropolitan Washington region. There are actually nine open heart surgery programs serving the Metropolitan Washington region. The three other programs not included in the proposed State Health Plan are located in Northern Virginia: Alexandria Hospital; Arlington Hospital; and Fairfax Hospital.

Table 4 displays data on the distribution of open heart surgery cases by hospital in the Metropolitan Washington and Metropolitan Baltimore regions, including and excluding Northern Virginia facilities. This analysis shows that in the Metropolitan Washington region four programs (Washington Hospital Center, Fairfax Hospital, Washington Adventist Hospital, and Georgetown University Hospital) together accounted for 91 percent of total 1998 cases. In the Metropolitan Baltimore region, the top four programs accounted for 89 percent of total cases in 1998. This data suggests that residents of the Metropolitan Washington region do not have fewer choices compared to Metropolitan Baltimore.

One of the differences in Metropolitan Washington as compared to Metropolitan Baltimore lies in the fact that each of three most recently approved open heart surgery programs in Metropolitan Washington have remained low volume programs after a decade or more of operation. As indicated in Table 5, the three new programs approved since 1989 in the Metropolitan Washington area have not yet achieved even minimum utilization levels.

Analysis of cardiac surgical utilization patterns in the Metropolitan Washington area shows that in 1998 the Washington Hospital Center accounted for about 46 percent of total open heart surgery cases, including Northern Virginia and about 67 percent excluding Northern Virginia. If the recent acquisition of Georgetown University Hospital by the parent company of the Washington Hospital Center, MedStar, is considered, then that system would account for about one-half of all cardiac surgery in the entire Metropolitan Washington region. Several of the comments received on the issue of system capacity suggested that the Washington Hospital Center capacity be limited to 40 percent of the need projected for the region. Staff believes that this concept has merit, but suggests that it would be more appropriate to set the cap at 50 percent of the planning region.

Staff Recommendation. Staff believes that the comments received on the measurement of program capacity suggest that the use of either physical operating room resources or historical utilization to quantify system capacity has significant limitations. Both approaches result in at best proxy indicators for system capacity. In the absence of a more comprehensive measure, staff recommends that the measurement of system capacity be changed as follows:

d. For new programs, capacity is defined as the greater of 350 cases or the actual number of cases during the first three years of a program's existence.

e. For programs older than three years, capacity is defined as the highest actual annual volume attained and reported by that program over the last three years subject to a market based constraint.

f. The capacity of any program cannot be greater than the higher of 800 cases or 50 percent of the projected gross need for the planning region.

(Refer to Table A-6 in Appendix 1 for the calculation of capacity using this recommended definition)

Table 4
Metropolitan Washington and Metropolitan Baltimore Open Heart Surgery Providers by Caseload, Percent of Total and Cumulative Percent: 1998

	With Northern Virginia			Without Northern Virginia		
Region/Hospital	**1998 Cases**	**Percent of Total**	**Cumulative Percent**	**1998 Cases**	**Percent of Cases**	**Cumulative Percent**
Metropolitan Washington Region						
Washington Hospital Center	2,709	45.90%		2,709	66.91%	
Fairfax Hospital	1564	26.50%	72.40%			
Washington Adventist Hospital	817	13.84%	86.24%	817	20.18%	87.08%
Georgetown University Hospital	301	5.10%	91.34%	301	7.43%	94.52%
Arlington Hospital	146	2.47%	93.82%			
Alexandria Hospital	143	2.42%	96.24%			
Prince George's Hospital Center	91	1.54%	97.78%	91	2.25%	96.76%
George Washington University Hospital	85	1.44%	99.22%	85	2.10%	98.86%
Howard University Hospital	46	0.78%	**100.00%**	46	1.14%	**100.00%**
Metropolitan Washington Total	**5,902**	100.00%		4,049	**100.00%**	
Metropolitan Baltimore Region						
St. Josephs Hospital	1,411	32.33%				
Johns Hopkins Hospital	1,146	26.25%				
Union Memorial Hospital	778	17.82%				
University of Maryland Hospital	553	12.67%				
Sinai Hospital of Baltimore	477	10.93%				
Metropolitan Baltimore Total	**4,365**	100.00%				

Source: Maryland Health Care Commission (Data reported for Maryland hospitals is from the Hospital Discharge Abstract Data Base; data reported for Washington, D.C. hospitals is from a discharge data base provided by the D.C. State Health Planning and Development Agency; and data reported for Northern Virginia hospitals is based on data from Virginia Hospital Licensing Reports, compiled by the Health Systems Agency of Northern Virginia.

Table 5
Open Heart Surgery Programs Approved Since 1989 and
Number of Cases: Metropolitan Washington

Hospital	Year Program Initiated	Year				
		1994	1995	1996	1997	1998
Prince George's Hospital Center	1990	59	81	90	61	91
Alexandria Hospital	1989	125	115	159	146	143
Arlington Hospital	1990	141	145	146	163	146

Source: Maryland Health Care Commission (Data reported for Maryland hospitals is from the Hospital Discharge Abstract Data Base for calendar years 1994-1998; and data reported for Northern Virginia hospitals for 1994-1998 is based on data from Virginia Hospital Licensing Reports, compiled by the Health Systems Agency of Northern Virginia.)

5. Patient Migration Patterns

Staff Analysis of Public Comments. The current methodology used to forecast projected open heart surgery cases assumes that existing regional patient migration patterns will remain constant between the base and target years of the forecast for all regions except Western Maryland. For in-migration from adjacent and out-of-state areas to programs in Maryland and Washington, D.C., the current methodology assumes that the actual number of patients will remain constant between the base and target years of the projection. In addition, the methodology assumes that the number of Washington, D.C. residents will remain constant between the base and target years of the need projection.

Comments regarding patient migration policies in the need projection methodology were received from seven organizations. Two of those organizations supported the current policy of holding patient migration patterns constant between the base and target years of the need forecast. Two other organizations indicated that patient migration is driven by factors such as the artificially constrained market and the ability of insurers to force patients into high volume hospitals. One commenter suggested that migration assumptions would be more accurate if made on a county by county basis, especially as it relates to potential changes in Western Maryland. Another commenter suggested that it would be appropriate to modify the existing migration patterns in the Metropolitan Washington area to change the allocation of future need such that at least 50 percent of the Maryland patients in the metropolitan Washington area are projected to be served by local Maryland hospitals.

Staff believes that existing migration patterns are the most appropriate guide in projecting future utilization. With respect to Western Maryland, staff believes that it is appropriate to

allocate cases in the updated need forecast consistent with the assumptions made in the previous plan upon which their approval was based. Once the Western Maryland program begins operation, the current allocation should be modified to reflect actual patient migration patterns. Staff would also agree that the Commission should consider migration patterns for angioplasty services as the role of angioplasty is examined and continues to evolve.

Staff Recommendation. Because a large number of factors influence where patients go for cardiac care services, actual utilization experience may be the best guide to future utilization patterns in the absence of being able to anticipate the impact of specific changes. Staff recommends that the Commission continue the policy of holding patient migration patterns constant between the base and target years of the need projection. It should be noted, however, that other aspects of the need methodology, notably measurement of capacity, may result in identification of need for new programs which will alter migration patterns in the future.

B. Quality of Care Policies

1. Minimum and Threshold Utilization Standards

a. Cardiac Surgery Services

Staff Analysis of Public Comments. The current State Health Plan establishes minimum and threshold volume standards for cardiac surgical programs. Thirteen organizations submitted comments concerning the minimum and threshold utilization standards for open heart surgery. Ten of the organizations supported a minimum utilization standard of 200 cases annually for open heart surgery programs. Three organizations suggested that the minimum utilization standard be increased to 350, 500 or more (as high as 800) open heart surgery cases annually. With respect to the threshold utilization standard, five organizations recommended a standard of 350 cases annually. Four organizations suggested that the threshold utilization standard be equivalent to the minimum utilization standard. Three organizations recommended a higher threshold utilization standard (e.g., 500-800 cases) than used in the current State Health Plan.

One of the quality standards used in the current State Health Plan indicates that adult cardiac surgical programs should perform a minimum of 200 cases annually to ensure quality of care. There is substantial support in the public comments received for maintaining this minimum utilization standard. Assuming 50 weeks of operation per year, this caseload level is equivalent to performing an average of four cardiac surgery procedures per 5-day week. While the minimum utilization standard of 200 cases annually used in the current State Health Plan is based on the original work of the Inter-Society Commission for Heart Disease Resources[1], this caseload level continues in practice to be the most universally accepted minimum standard for open heart surgery programs.

The current State Health Plan also establishes a threshold utilization standard which indicates that the establishment of a new cardiac surgery program should permit existing

[1]Wright, IS. Frederickson , DT. Eds. Cardiovascular Diseases. Guidelines for Prevention and Care. Reports of the Inter-Society Commission for Heart Disease Resources, 1972.

programs to maintain patient volumes of at least 350 cases annually. The use of a threshold standard, in combination with the minimum utilization standard, establishes a policy of requiring programs to perform well above the minimum level of cases before considering the development of additional program capacity. Although there was disagreement about whether the standard should be 350 versus 500-600 cases, the public comments received on this standard also suggest support for continuing to have a threshold utilization standard above the minimum use level. The recommendations prepared by the Technical Advisory Committee in 1999 suggest that cardiac surgery programs should perform at least 350 procedures annually within three years of beginning operation, and that approval of a new cardiac surgery program should not result in any program falling below 350 cases per year.

Staff Recommendation. For cardiac surgery services, a large volume of research studies have suggested lower mortality rates for programs performing higher volumes of procedures. Staff recommends cardiac surgical programs be required to perform a minimum of 200 cases annually to ensure quality of care; that programs be required to perform at least 350 procedures annually within three years of beginning operation; and that approval of a new cardiac surgery program not result in any program falling below 350 cases per year.

b. Coronary Angioplasty Services

Staff Analysis of Public Comments. While the current State Health Plan does not establish minimum volume standards for coronary angioplasty programs, guidelines prepared by the American College of Cardiology recommend that hospitals offering coronary angioplasty perform a minimum of 200 procedures annually.[2] One of the issues that the Commission requested comments on in the White Paper concerns whether it would be appropriate to add standards pertaining to recommended minimum and threshold volumes for coronary angioplasty services. Eleven organizations submitted comments regarding angioplasty volume standards. Three of those organizations questioned the legal ability of the Commission to adopt volume standards governing angioplasty services. Five organizations suggested that a minimum volume of 200 cases, consistent with recommendations of the American College of Cardiology, be used by the Commission. One commenter recommended that a minimum utilization standard of 100 cases annually be used to guide planning.

The 1999 Technical Advisory Committee reviewed seven major studies, using data sources ranging from registries to hospital discharge files, that examined the relationship between the volume of elective coronary angioplasty procedures and outcome. The outcome measures used by these studies include CABG surgery following a failed angioplasty procedure and/or death. Although several of these studies risk adjust outcomes based on whether the patient experienced an AMI, it is important to recognize that these studies refer to elective and not primary angioplasty. All seven of these studies suggest that hospitals performing higher volumes of coronary angioplasty procedures have fewer complications and/or deaths than low volume

[2] Ryan, TJ. Bauman WB. Kennedy JW. et al. Guidelines for Percutaneous Transluminal Coronary Angioplasty: A Report of the American Heart Association/American College of Cardiology Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures. *Circulation*. 1993; 88:2987-3007.

hospitals. The results from six of the studies indicate that the appropriate minimum volume benchmark is 400 cases annually.

In their review of these studies, the Technical Advisory Committee pointed out that it is important to recognize that most of these studies were done before the widespread use of stents and potent antiplatelet agents (the GpIIb/IIIa receptor antagonists) which have reduced the incidence of emergency CABG following failed angioplasty and death. Thus, while many of these studies report CABG rates of 2 percent or more in the high volume centers, currently this rate is three-fold lower, in the 0.7 percent range. Although there was a dissenting opinion included in their Final Report, the Technical Advisory Committee recommended that coronary angioplasty programs perform a minimum of 400 procedures annually.

For both elective and primary angioplasty services, studies have shown a greater incidence of complications and/or death in lower volume programs as compared with higher volume programs. Although there is less consensus on the appropriate minimum volume standard for angioplasty, staff believes that it would not be inappropriate to establish a minimum annual volume standard of 200 for elective angioplasty cases. Staff further believes that incorporating a minimum utilization standard for angioplasty that is consistent with recommendations of the American College of Cardiology in the State Health Plan is not inappropriate as a matter of law or health policy.

Staff Recommendation. For angioplasty services, research studies have suggested improved outcomes for programs performing higher volumes of procedures. Staff recommends that angioplasty programs be required to perform a minimum of 200 cases annually to ensure quality of care.

2. Enforcement of Minimum Volume Standards

Staff Analysis of Public Comments. In the current State Health Plan, Policy 1.3 states that a CON issued by the Commission for the establishment of a new cardiac surgery program will require as a condition of issuance that the program achieve minimum volume standards within 24-months of beginning operation and maintain the minimum utilization level in each subsequent year of operation. While this policy provides oversight for new cardiac surgery programs, it does not address the issue of existing programs operating below minimum utilization levels.

Eleven organizations provided public comments on the issue of enforcement of minimum volume standards. Several commenters suggested that there was a need to strengthen the ability of the Commission to enforce minimum volume standards. Other comments recommended that the Commission establish a process to review outcomes for programs that do not meet minimum utilization levels. It was also noted in the comments that the Certificate of Need program does not have the authority to revoke or suspend the CON of an existing and operating program for violation of a condition on the CON.

Staff Recommendation The relationship between the volume cardiac surgery cases and outcome suggests strongly that as a matter of public policy programs should meet minimum

utilization levels. Given the importance of this issue, staff recommends that the Commission continue to require as a condition of Certificate of Need approval that a cardiac surgery program achieve minimum volume standards established in the State Health Plan within 24-months of beginning operation and maintain the minimum utilization level in each subsequent year of operation. On the question of whether existing programs should be required to meet a similar standard, the staff will make a recommendation on whether to change the current statute as part of its recommendations on the Certificate of Need working paper.

3. Outcome Data Reporting

Staff Analysis of Public Comments. A number of states have developed and implemented strategies designed to improve the quality of specialized cardiac care services over the past decade. Alternative models implemented to date include public reporting of outcome data and the development of a voluntary consortium to promote data sharing and peer review. Eight organizations commenting on the White Paper addressed the issue of outcome data reporting. All of those organizations supported the need to collect and report outcome data. Three of the organizations commenting on this issue suggested that an independent consortium be formed to address outcome data reporting.

Data collected by the Commission in a national survey of Certificate of Need regulation for cardiovascular care indicate that a large number of States publish information on the use of cardiac services. The types of statewide data that are available for public access or use vary widely. In New York, for example, the State Department of Health has a Cardiac Surgery Reporting System that collects detailed data for all patients undergoing cardiac surgery and angioplasty. As part of this effort, a Cardiac Advisory Committee, composed of surgeons, cardiologists, and researchers, was formed to advise the Department of Health on the quality and appropriateness of cardiac surgery in New York. On an annual basis, the Department of Health in New York releases hospital-specific data on volumes and mortality rates. This publicly released information was expanded to include surgeon-specific risk-adjusted mortality rates in 1992. Similarly, the Pennsylvania Health Care Cost Containment Council annually releases public reports on coronary artery bypass graft surgery with risk-adjusted mortality rates for both hospitals and individual cardiac surgeons. Although public dissemination of outcome data has the potential to negatively impact referral patterns for cardiac surgery by encouraging the referral of high risk patients to out-of-state providers, there is evidence of improved outcomes following public release of performance data. Other approaches to quality improvement include the work done by the Northern New England Cardiovascular Disease Study Group and by cardiac surgery hospitals in Minnesota. In both New England and Minnesota, cardiac surgery programs have worked collaboratively to improve clinical outcomes through the collection and sharing of data.

The public comments received on the issue of outcome data reporting suggest substantial support for the concept of working to improve patient care through the collection and analysis of outcome data. While Maryland currently collects a uniform data set on all discharges from acute care hospitals, this data set does not have the clinical detail necessary to analyze and case mix-adjust cardiac surgery and angioplasty patients. As a consequence, it would be necessary to undertake an expanded data collection effort in Maryland to support the development of an on-

going outcome assessment process for cardiovascular services. Moreover, it would be important to study and evaluate alternate models for organizing and funding an outcome assessment function.

Staff Recommendation. Staff recommends that the Commission establish an Advisory Committee on Outcome Assessment in Cardiovascular Care to: (1) review available models and develop recommended approaches to outcome measurement in cardiovascular care, including cardiac surgery and angioplasty services; (2) develop a research agenda to advance the understanding of how cardiac care services should be organized to improve outcomes; and (3) develop recommendations on the appropriate governance, organizational structure, staffing, and funding for an on-going outcome assessment process for cardiovascular care. In establishing this Advisory Committee, the Commission should seek nominations from the Maryland Chapter of the American College of Cardiology, the Maryland Chapter of the American Heart Association, the Society of Thoracic Surgeons, the Medical-Chirurgical Faculty of Maryland, Maryland Hospital Association, and other appropriate organizations. Funding to support the work of the Advisory Committee on Outcome Assessment in Cardiovascular Care should be provided jointly by the Commission and hospitals.

4. Co-Location of Angioplasty and Open Heart Surgery Services

Staff Analysis of Public Comments. Comments regarding the co-location of angioplasty and open heart surgery services were submitted by sixteen organizations. Eight of those organizations recommended that the current policy requiring on-site cardiac surgery for angioplasty procedures with a limited exemption for primary angioplasty be maintained. Four organizations submitting comments suggested that the State Health Plan be modified to allow primary angioplasty in hospitals without cardiac surgery programs. The remaining four organizations suggested that the Commission consider modifying current policy to permit elective angioplasty in hospitals without on-site cardiac surgery.

The current State Health Plan for cardiac surgery and therapeutic catheterization services requires that hospitals providing coronary angioplasty services have on-site cardiac surgical backup. This policy was adopted in the 1990 cardiac surgery plan and has been reviewed with the assistance of the Technical Advisory Committee on two separate occasions since its original adoption. The 1997 Technical Advisory Committee, after considerable discussion and review of recent advances in the techniques used to perform angioplasty, concluded:

> *Although the rate of complications requiring emergency surgery has declined substantially in recent years, the TAC believes that the level of risk associated with performing angioplasty continues to require the presence of on-site cardiac surgical backup.*

The policy concerning the co-location of angioplasty and cardiac surgery was reviewed by the Technical Advisory Committee in 1999. This more recent review by the Technical Advisory Committee concluded with the following recommendations:

4.1 The Technical Advisory Committee recommends that coronary angioplasty only be performed in hospitals with on-site cardiac surgical backup.

4.4 The Technical Advisory Committee recommends that the policy regarding the co-location of coronary angioplasty and cardiac surgery services be reviewed on an on-going basis to reflect the results of current research and the experience of Maryland cardiovascular specialists.

While the State Health Plan for cardiac surgery and therapeutic catheterization services requires hospitals providing coronary angioplasty services to have on-site cardiac surgical backup, the plan also includes procedures for exempting certain research projects from this policy. Under these exemption procedures, the former Health Resources Planning Commission approved a request from Johns Hopkins University to permit selected Maryland hospitals participating in the Atlantic C-PORT primary angioplasty clinical trial to perform angioplasty on certain patients with acute myocardial infarction under the protocols of this research project.[3] Hospitals participating in this clinical trial may perform primary angioplasty without the requirement for on-site cardiac surgical backup. This exemption was originally granted for two years from an effective date of January 15, 1996, and was extended for one year in February 1998. In February 1999, the Commission extended the exemption through February 2001.

Between its initiation and December 1998, the C-PORT Project enrolled more than 400 patients in a randomized clinical trial comparing primary angioplasty with medical therapy. Preliminary results indicate that primary angioplasty can be safely performed without on-site cardiac surgery. No patient enrolled in the clinical trial to date has been referred for emergency coronary bypass surgery because of a complication of the angioplasty procedure. In terms of time to treatment, no other large scale clinical trial published to date has had better randomization-to-first-balloon inflation times than the C-PORT Project. In addition, the outcomes of angioplasty have been excellent with a success rate of 93 percent.[4]

The C-PORT Project was originally designed as a randomized clinical trial to compare primary angioplasty with medical therapy in patients with acute myocardial infarction treated at a range of hospital facilities. While early randomized trials were conducted principally in academic medical centers and involved only patients with ST-segment elevation infarction who were thrombolytic candidates, the C-PORT Project extended the comparison to acute myocardial infarction patients with ST-segment elevation considered thrombolytic ineligible.[5] At the time the C-PORT clinical trial was originally designed in 1996, there was limited experience in using the technique of coronary angioplasty to treat patients with acute myocardial infarction. Although there remain important questions on the role of primary angioplasty in treating acute myocardial infarction, this therapy has gained widespread acceptance among cardiologists as the

[3] The Atlantic C-PORT Project was initially referred to as the Baltimore C-PORT Project.

[4] Correspondence from Thomas Aversano, M.D., Associate Professor of Medicine, Johns Hopkins University Hospital, January 12, 1999.

[5] Aversano, T. Primary Angioplasty in the Treatment of Acute Myocardial Infarction. The Strategy of Chest Pain Units in Emergency Departments in the War Against Heart Attacks: Proceedings from the First Maryland Chest Pain Center Research Conference. Supplement to the *Maryland Medical Journal.* 88-93.

preferred approach for treating acute ST-segment elevation myocardial infarction when it can be performed. More recently, the use of primary angioplasty in treating acute myocardial infarction has been further improved and reinforced by the addition of coronary stents and potent antiplatelet agents, the GpIIb/IIIa receptor antagonists. Given these developments, the C-PORT Project stopped randomizing patients in August 1999.

At the same time, there have been significant advances in the medical management of acute myocardial infarction. Some recent data indicate, for example, that the combination of lower dose thrombolytics and the long-acting platelet glycoprotein IIb/IIIa inhibitor can achieve reperfusion rates similar to primary angioplasty.[6] This and other new therapies likely to be developed in the future suggest that the ultimate role of angioplasty versus medical therapy in managing acute myocardial infarction will continue to evolve, at least in the short term.

Given these considerations, the use of coronary angioplasty in treating patients with acute myocardial infarction continues to raise a number of important policy issues. Among those issues are whether access to primary angioplasty services should be expanded beyond the C-PORT hospitals. While the Maryland experience with primary angioplasty to date has provided numerous benefits, the Technical Advisory Committee felt that sufficient data were not yet available to warrant changing current State health policy to provide all hospitals with cardiac catheterization facilities with the ability to perform limited angioplasty procedures (i.e., primary angioplasty). The Technical Advisory Committee indicated that it would be preferable to use the expertise developed by the C-PORT participants to design and implement a statewide registry that would collect data critical to determining the optimum system of cardiovascular care.

Staff Recommendation. Staff recommends that: (1) the current policy requiring angioplasty procedures to be performed in hospitals with on-site cardiac surgery be maintained in the updated State Health Plan; and (2) the existing limited exemption for primary angioplasty performed in hospitals participating in the C-PORT project be continued. Staff believes that the C-PORT project has provided the opportunity for clinical research to guide State policy of oversight and that similar well-designed clinical research would contribute to improved patient care and more informed decision-making. Staff also believes that the Commission should consider a research project to assess whether it would be appropriate to modify current policy regarding the availability of cardiac surgical support for certain groups of elective angioplasty patients. This research project should be designed and implemented as a component of the Advisory Committee on Outcome Assessment in Cardiovascular Care. (Refer to Discussion in Part III.B.3)

[6] Kennedy, JW and Stadius, ML. Combined Thrombolytic and Platelet Glycoprotein IIb/IIIa Inhibitor Therapy for Acute Myocardial Infarction: Will Pharmacological Therapy Ever Equal Primary Angioplasty? *Circulation*. 1999;99:2714-2716.

C. Cost of Care Policies

1. Cost Effectiveness Standard

Staff Analysis of Public Comments. A significant component of the CON review process involves an assessment of the financial feasibility of a project conducted with the assistance of the Health Services Cost Review Commission. The current State Health Plan contains a cost-effectiveness standard that states the Commission will give preference in a comparative review to the applicant that offers the best balance between program effectiveness and costs to the health care system as a whole. Eleven organizations submitted comments on the cost effectiveness standard. Five of those organizations supported the cost effectiveness preference standard; five organizations recommended that the cost effectiveness preference standard be eliminated.

Historically, the cost effectivenss standard has been used to encourage hospitals interested in establishing new cardiac surgery programs to make competitive rate offers to the Health Services Cost Review Commission. The comments favoring elimination of the cost effectiveness preference standard indicated that pressures in the current managed care environment made this approach no longer necessary, that significant price competition already exists among cardiac surgery programs, and that the HSCRC has the regulatory authority to appropriately address rate issues. Comments in support of maintaining the cost effectiveness preference standard noted the past success of this policy approach in generating savings to the health care system. In their comments, the HSCRC indicated that the cost-effectiveness standard encourages continued competitiveness and keeps overall costs lower for consumers. HSRCR encouraged the Commission to retain this standard.

Given an established need for a new cardiac surgery service and similar, competing proposals, the cost effectiveness preference standard in the current State Health Plan encourages applicants to compete to offer the service at the lowest possible price. It could also be argued that having new providers make rate offers has the additional benefit of strengthening competition among existing providers and thus lowering costs throughout the system (i.e., for all patients).

Staff Recommendation. If need for additional cardiac surgery capacity is identified, staff believes that there is benefit to the public in encouraging applicants to make competitive rate offers as part of the Certificate of Need process. While the specific wording of this standard must be updated to be consistent with the recent changes to the HSCRC rate setting system, the policy approach has proven viable in the past and resulted in savings to the healthcare system that might not have otherwise been realized. At the same time, staff does not believe that cost considerations should receive greater weight than quality or access considerations. The cost effectiveness standard provides the Commission with the ability to give preference to the most cost effective applicant where other considerations in the review process are equal. Staff recommends that the cost effectiveness standard preference policy be continued in the updated State Health Plan.

D. Access to Care Policies

1. Travel Time Standard

Staff Analysis of Public Comments. Because cardiac surgery is a specialized health service appropriate for regional planning, a travel time standard of 2 hours, one-way driving time has traditionally been used as the benchmark for measuring geographic accessibility. Eight organizations submitted comments on the travel time standard. Two organizations supported the use of a two-hour travel time standard for cardiac surgery services. Several commenters suggested that travel time standards focus on access to angioplasty services for acute myocardial infarction patients. There was also the suggestion that time to treatment was potentially more relevant than a travel time standard.

The travel time standard included in the current State Health Plan is designed to provide a benchmark for assessing the availability of elective cardiac surgery services. Data included in the current State Health Plan analyzing travel time data to existing cardiac surgery programs indicates that virtually all Maryland residents are within two-hours, one-way driving time to at least one hospital that provides adult cardiac surgery services.

Staff Recommendation. Staff believes that it is appropriate to continue using a travel time standard in the updated State Health Plan for Cardiac Surgery and Therapeutic Catheterization Services. This standard should refer to elective cardiac surgery and angioplasty services. Staff believes that the current 2-hour, one-way driving time for 90 percent of the population is a reasonable standard. At the same time, staff recognizes the need to consider developing other access measures, including time to treatment goals for certain sub-sets of patients, as pointed out in several of the comments received on travel time. One of the issues that should be addressed by the Advisory Committee on Outcome Assessment in Cardiovascular Care is the optimum timeframe for initiating primary angioplasty given current research and clinical practice.

E. Other Policies

1. Eligibility to Meet New Need

Staff Analysis of Public Comments. Under the current plan, only hospitals without existing cardiac surgery programs are eligible to apply to meet new need. In other words, if the need projection calculation identifies a net need that is not less than the minimum utilization standard (i.e., 200 cases) then the Commission may consider the establishment of a new program. Comments on the issue of eligibility to meet new need were received from eleven organizations. Four organizations suggested that both existing and new providers be eligible to compete for new need. Six organizations recommended that only new providers be eligible to apply for new need.

Although the Commission is not required to approve a new cardiac surgery program with a net need identified, the current plan generally presumes that new need (i.e., 200 or more cases) is reserved for new providers as opposed to having existing providers expand capacity to meet

that need. Comments in support of having both existing and new providers compete for new need noted the potential benefits of increased competition and the need to minimize the risk associated with overly optimistic projection methodologies. On the other hand, comments in opposition to changing current policy noted the benefits of new providers in offering the public greater choice. There was also the suggestion that it may be advisable to give preference to applicants that offer a greater increase in choice, which might include hospitals that are independent of the region's existing providers, and possibly hospitals that will bring new open heart surgical groups into the region.

Under current law, the Commission regulates the number rather than the size of cardiac surgery programs. Given that the number of cardiac surgery operating rooms is not regulated under the Certificate of Need program, it could be argued that existing providers always have the ability to expand services to meet new need. This being the case it may be appropriate to consider establishing new programs rather than expand existing programs provided that minimum utilization standards can be met.

Staff Recommendation. Staff recommends that the current policy of limiting the eligibility to meet identified new need for cardiac surgery services to hospitals without existing programs be continued in the updated State Health Plan.

2. Hospital Size

Staff Analysis of Public Comments. In the policies established to guide approval of new cardiac surgery programs, the current State Health Plan addresses two aspects of overall facility capacity: (1) the size of the hospital; and (2) the size of the intensive care unit. The size of the hospital is measured by the average daily census for the most recent two years of available data. For the intensive care unit, size is measured by the number of staffed beds. Nine organizations submitted comments on the issue of hospital size. Seven organizations suggested that consideration be given to eliminating this standard. Several of the comments also recommended that the Commission consider using other measures to assess the suitability of a hospital to establish a open heart surgery program, including number of admissions, emergency room visits, and coronary service utilization.

Although the Commission may consider evidence as to why this policy should be waived, under the current State Health Plan applicants for new cardiac surgery programs must have an average daily census of 100 patients over the past two years and an 8-bed fully staff ICU. Data for the 12-month period ending in February 2000 indicates that 31 of the 47 licensed acute care hospitals in the State had an average daily census of 100 or more patients. Under this policy, most of the hospitals in the State would be eligible to develop a new cardiac surgery program if need were identified in the State Health Plan. An alternative approach outlined in the White Paper would be to increase the facility size policy by requiring potential new applicants for cardiac surgery programs to have an average daily census of 200 rather than 100 patients. This policy would limit the number of hospitals that would be eligible to apply for a new open heart surgery program to the larger facilities. Eleven of the 47 acute care hospitals in the State,

including 7 of the 8 Maryland open heart surgery programs, had an average daily census of 200 or more patients during the 12-month period, March 1999-February 2000.

The ability of a hospital to successfully develop and implement a cardiac surgery program is clearly influenced by a large number of factors. While the size of the hospital alone would not determine the success of an open-heart surgery program, there are advantages to having an infrastructure that can support a higher volume program. Hospital bed size is one indicator of infrastructure that would potentially have relevance in considering the development of open heart surgery programs. At the same time, there are clearly other factors that have significance, including the volume of cardiac patients currently treated within the hospital.

Staff Recommendation. Staff recommends that the Commission: (1) continue to require applicants for new cardiac surgery programs to have an average daily census of at least 100 patients; (2) delete the policy pertaining to the size of the intensive care unit; and (3) develop indicators pertaining to the volume of cardiac patients for inclusion in the State Health Plan. With respect to the Size of Hospital policy, staff believes that the Commission should retain the ability to consider evidence as to why this policy should be waived.

3. Number of New Programs Allowed

Staff Analysis of Public Comments. The current State Health Plan includes a policy that permits the Commission to only approve one new open heart surgery program at a time in a regional service area. In the White Paper, the Commission sought comments on whether this policy should be maintain in the updated State Health Plan. A total of twelve organizations submitted comments on this issue. Of those comments, five organizations supported the current policy of limiting the number of new programs approved in a region at one time. Six organizations suggested that the policy limiting the number of new programs approved at one time be eliminated.

Comments opposed to the current policy indicated that if need were sufficient to support more than one new program that it would be inappropriate to artificially limit the number of programs approved. In addition, several comments suggested that the one program at a time approach resulted in additional expense and wasted time because of the need to convene multiple Certificate of Need hearings. Several of the commenters also characterized the fact that one of the three open heart surgery programs opened over the past decade had not reached minimum volume levels as evidence that the planning system has failed (i.e., a 33 percent failure rate). Those commenting in support of the policy to limit the number of new programs developed at one time cited the need to minimize the disruption due to loss of staff or program volumes that could potentially occur if multiple programs were initiated at one time.

Staff believes that the policy providing that only one new program will be approved at a time in each regional service area recognizes the importance of ensuring that cardiac surgery programs meet utilization standards. In this manner, a new program would not have to compete during a startup phase with another new program. Although the impact of a new program on existing versus other new programs can be debated, it is clear that multiple new providers would

potentially negatively impact staffing issues. Given the shorter planning horizon recommended for the plan, it could also be argued that there would be advantages to maintaining the one at time approach combined with more frequent updates of the need projections. In this manner, emerging trends in the utilization of cardiac services could be monitored and reflected in future updates of the need projections and planning policies.

With respect to the comments characterizing the planning process for cardiac surgery as a failure, staff points out that seven of the eight cardiac surgery programs in Maryland have volumes well above minimum utilization levels. In 1999, 90 percent of the cardiac surgery cases performed in Maryland and Washington, D.C. hospitals occurred in high volume programs that exceeded minimum utilization standards.

Staff Recommendation. Staff recommends that the Commission continue the policy of permitting the approval of one new cardiac surgery program at a time in each regional service area.

4. Preference Standards in Comparative Reviews

Staff Analysis of Public Comments. For comparative Certificate of Need reviews, the State Health Plan outlines several preference standards in addition to the cost effectiveness standard discussed earlier. Those standards include giving preference to applicants with an established cardiovascular disease prevention and early diagnosis program that includes provisions for educating patients about treatment options; and giving preference to applicants with an established cardiovascular disease prevention and early diagnosis program with particular outreach to minority and indigent patients in the hospital's regional service area.

Eleven organizations submitted comments to the Commission regarding these preference standards. Several of the commenters noted that it would be appropriate for the Commission to give preference to programs serving minority and indigent populations. Other comments supported the concepts set forth in the preference standards (e.g., prevention, education, outreach to disadvantaged populations) but suggested that the preference standards themselves be eliminated. Several of the comments received on the issue of preference standards also noted the need to address the continued unexplained evidence of lower use rates for minority populations as well as women when compared to Caucasian men. Finally, one of the commenters recommended that an additional preference be added in connection with applicants whose proposals involve a research project of national significance.

Staff believes that the preference standards provide a tool for encouraging prospective applicants to address important health policy issues. In the area of cardiac care services, for example, use rates for African-Americans have historically been well below those experienced by the non-African American population. While the precise reasons for these differences are not well understood, giving preference to applicants with a demonstrated record of serving minority populations may provide positive results in reducing the disparity in use rates. Because cardiovascular diseases have a number of risk factors that can be effectively addressed through prevention strategies, giving preference in a comparative review to applicants with established

disease prevention and early diagnosis programs may also have merit. In addition to these two areas, there was a suggestion that another preference standard be added in the updated State Health Plan chapter for applicants whose proposals involve a research project of national significance. Staff believes this suggestion has merit, but would suggest that research projects of both local and national significance should be considered.

Staff Recommendation. From a planning perspective, the use of preference standards in a highly competitive, comparative Certificate of Need review can provide an incentive for hospitals to address important public policy issues. For this reason, staff recommends that the preference standards designed to promote cardiovascular disease prevention and outreach to minority populations be maintained in the updated State Health Plan. In addition, the updated State Health Plan should include a preference standard designed to encourage research in the area of cardiovascular diseases.

5. Exemptions from State Health Plan Policies

Staff Analysis of Public Comments. In 1995, the former Health Resources Planning Commission received a request from a cardiologist at Johns Hopkins University for permission to conduct a research study involving primary angioplasty services in community hospitals without on-site cardiac surgical backup. Because the State Health Plan specifically required that angioplasty procedures be performed only in hospitals with on-site cardiac surgery services, this study could not have been conducted without a modification to the planning policies. In considering this issue, the Commission outlined a procedure for granting exemptions from certain State Health Plan policies. The State Health Plan was subsequently amended to include this exemption policy.

In updating the State Health Plan, one of the issues that requires consideration concerns whether the current approach to exempting projects from planning policies should be maintained, modified, or eliminated. A total of ten organizations submitted comments on the exemption policies included in the existing State Health Plan. Nine of the ten organizations supported continuing the ability for the full Commission to waive policies in the State Health Plan for research projects of a limited duration.

Under the current plan, research projects may be considered for an exemption from certain policies (i.e., planning and program policies) to meet the special needs and circumstances of biomedical research projects which are designed to meet a national need, and for which local conditions offer special advantages. In order to be eligible for this exemption, the plan outlines several conditions: (1) prior to initiation of the project the research proposal must be reviewed by each participating facility's Institutional Review Board; (2) the research proposal must receive a majority of its funding from a federal agency, other public agency, or private non-profit foundation that has authority over research on human subjects; and (3) the funding agency or foundation must have no financial affiliation with entities that stand to gain economically from the conduct or outcome of the trial.

Staff Recommendation. The current exemption policy maintains flexibility for the Commission to consider innovative research projects involving emerging technology without compromising important planning policies. Staff recommends that this policy be incorporated in the updated State Health Plan with a modification to permit hospitals to contribute funding for research projects under appropriate circumstances. This exemption policy would provide the Commission with the ability to conduct a study on whether it would be appropriate to modify current policy regarding the availability of cardiac surgical support for certain groups of elective angioplasty patients. (Refer to Discussion in III.B.4)

6. Relocation of Existing Cardiac Surgery Capacity within Merged Asset Hospital Systems

Staff Analysis of Public Comments. Consolidation and merger activity in the health care industry is proceeding a rapid pace in Maryland and across the nation. In Maryland, there are now 11 merged hospital systems. These systems, defined as multiple-hospital systems under common management and governance, include about one-half of the 47 licensed acute care hospitals in the State. State health policy favors hospital mergers by providing incentives that exempt certain types of otherwise reviewable projects from the requirement to obtain a CON. The ability to obtain an exemption from the requirement to receive a CON provides an incentive for hospital consolidations and mergers by establishing a more limited, expedited review process for changes in hospital beds or services, and major capital expenditures.

Given the desire to promote public policy incentives for hospitals to downsize and reconfigure services, an issue that requires consideration in updating the cardiac surgery plan chapter concerns the policy governing the relocation of cardiac surgery services within merged asset systems. Twelve organizations submitted comments on the policy governing relocation of cardiac surgery services in the current State Health Plan. Ten of those organizations supported current policy that does not permit relocations without obtaining a Certificate of Need. Two organizations suggested that the current prohibition might be too broad and that there may be benefits to permitting merged asset hospitals to relocate an entire, existing cardiac surgery program to another hospital under an exemption process.

Because the potential relocation or dividing of cardiac surgery programs may result in proliferation of programs in the absence of need and undermine the principles of regional planning for highly specialized services, the policies in the current State Health Plan prohibit the relocation of all or part of an existing cardiac surgery program within a merged asset system without obtaining a Certificate of Need. Given the small number of programs offering cardiac surgery, it seems appropriate that changes in the location of those programs be the subject of a full Certificate of Need review.

Staff Recommendation. Staff recommends that the Commission maintain the policy that a merged asset hospital system may not relocate any part of an existing cardiac surgery program to another hospital within its system without obtaining a Certificate of Need.

Appendix 1

Calculation of Projected Need for Cardiac Surgery Programs By Regional Service Area: Target Year 2002

Table A-1

Adult Open Heart Surgery Use Rates per 100,000 Population and Percent Change by Age Group and Region: Maryland, 1997-1999

Region	15-44 Years		45-64 Years		65 + Years	
	Use Rate	% Change	Use Rate	% Change	Use Rate	% Change
WESTERN MARYLAND						
1999	8.91		298.07		632.32	
METRO WASHINGTON						
1997	9.93		193.07		626.90	
1998	14.03	41.29%	191.77	-0.67%	653.71	4.28%
1999	12.17	-13.26%	199.33	3.94%	651.71	-0.31%
Average Annual Change		*14.02%*		*1.63%*		*1.99%*
METRO BALTIMORE						
1997	18.42		292.70		821.86	
1998	18.10	-1.74%	254.62	-13.01%	812.58	-1.13%
1999	16.33	-9.78%	259.63	1.97%	795.74	-2.07%
Average Annual Change		*-5.76%*		*-5.52%*		*-1.60%*
EASTERN SHORE						
1997	12.03		216.01		587.05	
1998	14.01	16.46%	212.98	-1.40%	651.97	11.06%
1999	19.32	37.90%	232.47	9.15%	608.38	-6.69%
Average Annual Change		*27.18%*		*3.87%*		*2.19%*

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Table A-2

Total Projected Adult Open Heart Surgery Cases By Region of Patient Origin, 2002

Region of Patient Residence	Age Group	2002 Population	Projected Use Rate	Projected 2002 OHS Cases
Western Maryland (1)	15-44	170,260	8.91	15
	45-64	103,358	298.07	308
	65+	51,398	632.32	325
Total		325,016		648
Metropolitan Baltimore (2)	15-44	1,026,671	13.67	140
	45-64	613,482	218.96	1,343
	65+	280,794	758.15	2,129
Total		1,920,946		3,612
Eastern Shore (2)	15-44	150,570	39.74	60
	45-64	98,581	260.52	257
	65+	53,486	649.23	347
Total		302,637		664
Metropolitan Washington Montgomery & Southern Maryland (2)	15-44	854,917	18.04	154
	45-64	495,436	209.24	1,037
	65+	180,150	691.40	1,246
		1,530,503		2,436
Washington, DC (3)				581
Total				3,017
TOTAL				**7,942**

NOTES:

(1) The projected use rate for Western Maryland residents reflects the 1999 base year experience.

(2) The projected use rates for Metropolitan Baltimore, Eastern Shore, and Metropolitan Washington are based on the average annual percent change between 1997-1999.

(3) The projection for Washington, D.C. residents reflects estimated 1999 base year cases.

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Table A-3

Base Year (1999) Patient Migration for Adult Open Heart Surgery: Maryland and Washington, D.C. Residents

Patient Origin by Region	Total and Percent Cases Performed by Region of Care				TOTAL
	Metro D.C.	Metro Baltimore	Eastern Shore	Western Maryland	
Western Maryland	441 *72.06%*	170 *27.78%*	1 *0.16%*	0 *0.00%*	612 *100.00%*
Metrpolitan Baltimore	399 *10.42%*	3,429 *89.58%*	0 *0.00%*	0 *0.00%*	3,828 *100.00%*
Eastern Shore	73 *13.18%*	219 *39.53%*	262 *47.29%*	0 *0.00%*	554 *100.00%*
Metropolitan Washington					
Washington, D.C.	578 *99.48%*	3 *0.52%*	0 *0.00%*	0 *0.00%*	581 *100.00%*
Montgomery and Southern Md. Co.	2,045 *97.75%*	45 *2.15%*	2 *0.10%*	0 *0.00%*	2,092 *100.00%*
Total Metro Washington	2,623 *98.13%*	48 *1.80%*	2 *0.07%*	0 *0.00%*	2,673 *100.00%*

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Table A-4

Adjusted Patient Migration Proportion for Target Year (2002) Allocation of Projected Cases

Patient Origin by Region	Percent Cases Allocated to Region of Care				TOTAL
	Metro Washington	Metro Baltimore	Eastern Shore	Western Maryland	
Western Maryland	30.90%	24.10%	0.00%	45.00%	100.00%
Metropolitan Baltimore	10.42%	89.58%	0.00%	0.00%	100.00%
Eastern Shore	13.18%	39.53%	47.29%	0.00%	100.00%
Metropolitan Washington	98.13%	1.80%	0.07%	0.00%	100.00%

Table A-5

Allocation of Projected Need for Adult Cardiac Surgery to Regional Service Areas: Target Year 2002

Region of Patient Origin	Percent Distribution by Region of Care								TOTAL
	Metro D.C.		Metro Baltimore		Eastern Shore		Western Maryland		
	Cases	% Allocated	Cases	% Allocated	Cases	% Allocate	Cases	% Allocated	
Western Maryland	200	0.3090	156	0.241	0	0	292	0.45	648
Metropolitan Baltimore	376	0.1042	3,236	0.8958	0	0	0	0	3,612
Eastern Shore	88	0.1318	262	0.3953	314	0.4729	0	0	664
Metropolitan Washington	2,961	0.9813	54	0.018	2	0.0007	0	0	3,017
Out-of-State	626		572		296				1,494
Total by Region of Care	**4,251**		**4,281**		**612**		**292**		**9,435**

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Table A-6

Calculation of Net Need for Adult Cardiac Surgery by Regional Service Area: Target Year 2002

Hospital by Region	Existing and CON Approved Capacity	Projected Cases (2002)	Net Need (2002)	New Program Considered
Western Maryland	350	292	(58)	No
Metropolitan Washington				
Prince George's Hospital Center	120			
Washington Adventist	899			
Georgetown Univ. Hospital	328			
George Wash. Univ. Hospital	85			
Howard University Hospital (1)	50			
Washington Hospital Center	2,126			
Total	3,608	4,251	643	Yes
Metropolitan Baltimore				
Johns Hopkins Hospital	1,146			
Sinai Hospital of Baltimore	541			
St. Josephs Hospital	1,411			
Union Memorial Hospital	893			
University of Maryland Hospital	775			
Total	4,766	4,281	(485)	No
Eastern Shore				
Peninsula Regional Medical Ctr.	561	612	51	No

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